K093644

DEC 1 8 2009

510(k) Summary of Safety and Effectiveness:
Restoration® ADM System X3® Acetabular Insert

Proprietary Name:	Restoration® ADM System X3® Acetabular Insert
Common Name:	Artificial Hip Replacement Components - Acetabular
Classification Name and Reference:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353
Proposed Regulatory Class:	Class II
Product Codes:	87 MEH, 87 LZO
For Information contact:	Avital Merl-Margulies Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6365 Fax: (201) 831-3365
Date Prepared:	November 18, 2009

Description:
The Restoration® Anatomic Dual Mobility (ADM) System X3® Acetabular Insert is a component of the Restoration® ADM System. The Restoration® ADM X3® Acetabular Insert retains a femoral head. The outer diameter of the insert articulates on the inner surface of the polished metal acetabular cup. The polyethylene insert therefore functions as a bipolar head as there are two articulating surfaces.

Intended Use:
The Restoration® ADM system X3® Acetabular Insert is a sterile, single-use device intended for use in primary and revision total hip arthroplasty to alleviate pain and restore function. This device is intended to be used only with any currently available Howmedica Osteonics 28 mm diameter femoral heads.

Indications:
The indications for use for total hip arthroplasty include:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2) Rheumatoid arthritis;
3) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed;
5) Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
6) Dislocation risks

This acetabular cup is intended for cementless use only.

Proposed Modification:
Addition of new polyethylene components of a modified sequentially crosslinked and annealed material which has undergone a STERRAD gas plasma sterilization.

Device Description:
The device includes the acetabular inserts of a total hip system. These components are used for the replacement of the bearing surface of the acetabulum to relieve pain, instability, and the restriction of motion due to degenerative bone disease, including osteoarthritis, rheumatoid arthritis, failure of other devices, or trauma.

Summary of Data:
A risk analysis and research and development testing have been performed to demonstrate equivalence of the subject products to the predicate devices. The testing includes material properties characterization, hip simulated wear testing, and disassembly force evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
% Ms. Avital Merl-Margulies
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

DEC 18 2009

Re: K093644
Trade/Device Name: Restoration® ADM System X3® Acetabular Insert
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Regulatory Class: Class II
Product Code: MEH, LZO
Dated: November 24, 2009
Received: November 25, 2009

Dear Ms. Merl-Margulies:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093644

Device Name: Restoration® ADM System X3® Acetabular Insert

Indications for Use:

The indications for use of the total hip arthroplasty include:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2) Rheumatoid arthritis
3) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed;
5) Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
6) Dislocation risks

This acetabular cup is intended for cementless use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093644